REMARKS

Formal Matters

The Office Action mailed August 31, 2001 (Paper No. 9) correctly stated on page 1 that claims 24-30 were pending in the application. The Examiner erroneously stated on page 2 (items 1 and 2) and page 4 (item 5), however, that claims 25-30 were pending. Applicants reiterate that claims 24-30 were pending in the application at the time the Office was issued and treat the rejection as it may be applied to claims 24-30 and the currently pending claims.

Claims 24, 25, and 27 are pending in the application. Claims 26 and 29-30 have been canceled without prejudice to later prosecution in a continuing or divisional application. Claims 24, 25, and 27 are amended merely to advance prosecution of the claims and to place them in condition for appeal should an appeal become necessary. Support for the amendments to the claims is found throughout the specification such as in previously pending, now canceled claim 29. No new matter is added by the amendments. The Examiner is respectfully requested to enter the amendments.

Rejection Under 35 U.S.C. §112, First Paragraph

Claims 25-30 are rejected under 35 U.S.C. §112, first paragraph, as allegedly not enabled by the specification. Applicants respectfully note that claims 24-30 were pending in the application and traverse the rejection as applied to claims 24-30 and as it might be applied to the currently pending claims for the reasons provided below. Claims 26 and 29-30 are canceled without prejudice to later prosecution, thereby rendering moot their rejection.

Applicants have amended pending claims 24, 25, and 27 to recite a mouse wherein the CT-1 gene of the animal is defective or absent. Support for the amendment is found throughout the specification, such as at previously pending, now canceled, claim 29. As knock-out mice were well-known in the literature at the time the instant application was filed, one of ordinary skill in the art is readily guided by Applicant's disclosure to generate the claimed subject matter.

With due respect, the Examiner erroneously states that the CT-1 deficient mouse of the invention "will not have any use other than being used as a wild-type mouse" (page 3, lines 19-21

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of the Office Action), having based this error on a misinterpretation of the Oppenheimer et al. reference (J. Neuroscience 21(4):1283-1291 (2001)). First, this concern is unrelated to enablement under section 112, first paragraph, and should be withdrawn as inapplicable. Even if this aspect of the rejection is not withdrawn as inapplicable, it should be withdrawn because it fails to recognize that the CT-1 knock-out mice described by Oppenheimer et al. do, indeed, have features different than wild-type mice. For, example, in the last sentence of the section entitled "Generation of *ct-1*-deficient mice," the authors point out that CT-1 was not expressed in mice homozygous for this mutation - clearly different from a wild-type mouse. In addition, the authors show that motoneuron loss was enhanced by 29% at birth and by >40% at postnatal day 9 in *ct-1*-/- mice and that 4-monthold *ct-1*-/- mice showed a significant reduction in muscle strength relative to wild-type mice (see the section entitled "Enhanced loss of motoneurons in the spinal cord and brainstem motor nuclei of ct-1-deficient mice occurs between embryonic day 13 and birth."). Thus, *ct-1*-/- mice possess neurological disorders and are distinguishable from wild-type mice. The *ct-1*-/- mice are clearly useful as model organisms of CT-1 deficiency.

Based on the above discussion, Applicants respectfully submit that the rejection should be withdrawn. Allowance of the claims is respectfully requested.



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SUMMARY

Claims 24, 25, and 27 are pending in the application. Claims 26 and 29-30 have been canceled without prejudice to later prosecution. Claims 24, 25, and 27 are amended merely to advance prosecution of the claims and to place them in condition for appeal should an appeal become necessary. No new matter is added by the amendments and the Examiner is respectfully requested to enter them.

The only remaining rejection in the Office Action was a rejection of claims 25-30 under 35 U.S.C. § 112, first paragraph, all other rejections having been overcome and withdrawn. Applicants have overcome the section 112, first paragraph in the present response and respectfully request withdrawal of this rejection.

If in the opinion of the Examiner, a **telephone conference** would expedite the prosecution of the subject application, the Examiner is **strongly encouraged** to call the undersigned at the number indicated below.

This response is timely submitted with a transmittal letter and petition for a three month extension of time. In the unlikely event that this document is separated from the transmittal letter, applicants petition the Commissioner to authorize charging our Deposit Account 07-0630 for any fees required or credits due and any extensions of time necessary to maintain the pendency of this application.

Respectfully submitted, GENENTECH, INC.

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PATENT TRADEMARK OFFICE

Doc. # 97518

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

In the Claims:

Claims 24, 25, and 27 are amended as follows, wherein strikeout in brackets $[\theta\theta]$ indicates deleted terminology and underling, 00, indicates added terminology.

- 24. (Amended) A [non-human animal] mouse comprising homologously recombined DNA wherein the CT-1 gene of the animal is altered such that CT-1 polypeptide of the animal is defective or absent.
- 25. (Amended) The [animal] mouse of claim 24 wherein the [animal] mouse is characterized by the development of a pathological condition due to absence of the CT-1 polypeptide.
- 27. (Amended) The [animal] mouse of claim 25 wherein the pathological condition is a neurological disorder.

